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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,887	07/17/2003	Ulrich Posanski	4-20017E	7665

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,887	POSANSKI, ULRICH	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12 and 14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 12 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed October 22, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

Claims 11, 12, 14 and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sehgal et al. (US 3,993,749) in view of Uomoto et al. (US 5,380,745).

Sehgal et al. disclose rapamycin compositions (Abstract). Rapamycin is an antibiotic that is substantially insoluble in water. It has profound antifungal activity and has a relatively low order of toxicity (col. 6, lines 46-49). It may be administered orally in the form of solutions or suspensions (col. 4, lines 18-38).

The reference differs from the instant claims insofar as it does not disclose formulations of solutions and suspensions comprising components a), b) and c) in the recited amounts.

Uomoto et al. disclose medicinal compositions comprising a practically water-insoluble compound. The compositions may comprise either one or more compounds selected from either or both nonionic surfactants and fats and oils (Abstract). The compositions elevate water-solubility of the active compound and thus enhance the effect (Abstract). The nonionic surfactant may comprise 5 to 50 parts by weight of the active compound. Surfactants include sorbitan fatty acid esters, polyoxyethylene sorbitan fatty acid esters and polyglycerol fatty acid esters (col. 2, lines 48-61). Oils include soybean oil, rapeseed oil, castor oil and cotton seed oil (col. 2, lines 62-66). Example 9 discloses a mixture comprising 20 g (40%) soybean oil, 12.5 g (25%) of polyoxyethylene (20) monostearate, 12.5 g (25%) of sorbitan monoleate and 2 g (4%) of the active agent. The example encompasses the instant claims. The compositions may be incorporated into capsules (see Example 3).

The reference differs from the instant claims insofar as it does not disclose the compositions comprise a therapeutic agent chosen from rapamycin, tacrolimus or mycophenolate-mofetil.

In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, “obviousness to try” such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to make an oral compositions comprising rapamycin with good solubility of rapamycin and good bioavailability. Accordingly, it would have

been obvious to have formulated an oral pharmaceutical composition comprising the rapamycin of Sehgal et al. with the vehicles of Uomoto et al. motivated by the desire to use a vehicle that can elevate water-solubility of the active compound and thus enhance the effect of the rapamycin as disclosed by Uomoto et al.

2) Claims 11, 12 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sehgal et al. (US 3,993,749) in view of Akiyama et al. (US 5,576,025) in further view of Uomoto et al. (US 5,380,745).

Sehgal et al. is discussed above and differ from the instant claims insofar as they do not disclose the compositions comprise components a), b) and c) in the recited amounts.

Akiyama et al. disclose compositions comprising a polyglycerol fatty acid and/or a lipid and an active agent (Abstract). Such composition can adhere to the digestive tract and remain there for a prolonged period of time, thereby increasing the bioavailability of the active ingredient. The compositions may comprise oleyl glycerides such as oleyl mono(hexa)glyceride (col. 4, lines 51-55), encompassing claim 15. The amount of polyglycerol fatty acids in the matrix ranges 0.001 to 10,000 parts by weight of the active agent. The amount of lipid in the matrix ranges from 0.01 to 100 parts by weight of the active agent (col. 9, lines 51-67). Lipids include cottonseed oil and soybean oil. The amount of active in the matrix ranges from 0.0001 to 95% and includes ibuprofen col. 6, line 8). Surfactants may be used in the compositions and include

polyoxyethylene-sorbitan fatty acid esters and sodium alkyl sulfates (col. 10, lines 20-23).

The reference differs from the instant claims insofar as it does not disclose the amount of surfactant that may be used in the compositions or disclose the compositions comprise a therapeutic agent chosen from rapamycin, tacrolimus or mycophenolate-mofetil.

In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to make an oral compositions comprising rapamycin with good solubility of rapamycin and good bioavailability. Accordingly, it would have been obvious to have formulated an oral pharmaceutical composition comprising the rapamycin of Sehgal et al. with the vehicles of Akiyama et al. motivated by the desire to make a rapamycin composition that can adhere to the digestive tract and remain there for a prolonged period of time, thereby increasing the bioavailability of the active ingredient as disclosed by Akiyama et al.

Sehgal et al. in view of Akiyama et al. differ from the instant claims insofar as it does not disclose the amount of surfactant that may be used in the compositions.

Uomoto et al. is discussed above and differs from the instant claims insofar as it does not disclose the compositions comprise a therapeutic agent chosen from

rapamycin, tacrolimus or mycophenolate-mofetil or the specific polyglycerol fatty acid esters of claim 15.

It would have been obvious to one of ordinary skill in the art to have used the surfactant in the recited amount in the composition of the combined teachings of Sehgal et al. in view of Akiyama et al. motivated by the desire to use amounts disclosed by the art as suitable for use in compositions comprising poorly soluble active agents.

In regard to the exact amounts recited in the instant claims, polyglycerol fatty acids and lipids may be used in combination with a nonionic surfactant. The amounts as disclosed by the combination of references comprise polyglycerol fatty acids from 0.001 to 10,000 parts by weight of the active agent, lipid from 0.01 to 100 parts by weight of the active agent and the nonionic surfactant from 5 to 50 parts by weight of the active agent. These amounts read on a 1:1:1:1, polyglycerol fatty acid, lipid, nonionic surfactant, and active agent, and are encompassed by the instant claims. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). The amounts as recited in the instant claims are obvious in view of the amounts disclosed by the combination of references disclosing the amount of polyglycerol fatty acid, lipid (oil) and a nonionic surfactant such as one having a HLB above 10 such as polyoxyethylene-sorbitan fatty acid esters consistent with In re Peterson.

Claims 11, 12 and 14-22 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612